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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,956	01/10/2006	Bernd Karl Friedrich Kremer	18724.009	3600

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ARNOLD & PORTER LLP
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EXAMINER

JUEDES, AMYE

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

07/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/563,956

Applicant(s)

KREMER ET AL.

Examiner

AMY E. JUEDES

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54 and 73-99 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 54 and 73-99 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

1. Applicant's amendment, filed 4/17/08, is acknowledged.

Claims 38-53 and 55-72 have been cancelled.

Claims 54 and 77 have been amended.

Claims 78-99 have been added.

Claims 54 and 73-99 are pending.

2. Applicant's election with traverse of group III, drawn to a method for treating a disease comprising administering a self tolerance inducing cell, claims 54 and 73-77, in the reply filed on 5/8/08, is acknowledged.

Applicant's traversal is on the grounds that it would not be an undue burden to examine the entire application. This is not found persuasive because undue burden is irrelevant to the restriction practice for cases filed under 35 U.S.C 371 (see MPEP Chapter 1800). Applicant further the Examiner has mistaken the invention of groups III and IV and the technical feature described in Munn et al. to be the same. Applicant has not provided any specific argument as to how the claimed invention differs from that described by Munn et al. Furthermore, the restriction requirement states that the inventions of groups I and II have no special technical feature that defined the contribution over the prior art of Munn et al. Thus, unity of invention of the entire claimed invention (i.e. groups I-V) is lacking, since all of the claims do not share a special technical feature that defines the contribution as a whole over the prior art.

The requirement is still deemed proper and is therefore made FINAL.

3. It is noted that Applicant has cancelled all of the claims drawn to the non-elected invention. However, Applicant's amendment adding new claims 78-99 has necessitated a further requirement for restriction, outlined below.

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

5. The species are as follows:

Applicant is further required to elect:

a specific type of transplant acceptance inducing cell, wherein the cell expresses CD3/CD14, FoxP3, CTLA4, or $\alpha\beta 7$ integrin,

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a specific type of disease associated with disturbed self-tolerance to be treated, selected from the group consisting of allergy and autoimmune disease,

and list all claims readable thereon including those subsequently added.

6. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

7. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reason:

The species of method comprising administering a cell expressing CD3 and CD14 has no special technical feature that defined the contribution over the prior art of U.S. Patent 5,766,920.

The '920 patent teaches a method of treating autoimmune disease in a patient comprising isolating mononuclear cells from peripheral blood of the patient, culturing said mononuclear cells with a culture supernatant (T3CS) comprising IFN- γ and M-CSF, and administering the cells to the patient (see column 2, 5, and 8 in particular). The '920 patent further teaches that the isolated mononuclear cells comprise monocytes (see column 2 in particular). Thus, the cells have been made by a process identical to that recited in the instant claims and must inherently express CD3 and CD14.

8. Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

9. Accordingly, the species are not so linked as to form a single general inventive concept and restriction is proper.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 6am - 2pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be

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reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Amy E. Juedes/
Examiner, Art Unit 1644